REMARKS/ARGUMENTS

Applicants appreciate the thorough examination of their invention and are attempting in this amendment to address the concerns expressed by the Examiner. Applicants believe that the invention of the claims is now clearly distinguishable from the inventions of the references.

Applicants note that a Declaration signed by both inventors has not been made of record and have therefore enclosed one herewith along with the required late filing fee of $65. A petition to add the second inventor was filed on December 19, 2003.

Applicants also enclose Power of Attorney forms herewith.

With respect to the claim rejections under 35 U.S.C. 103(a), the applicants note that the new and amended claims (and dependent original claims) are patentable over Mullen (5,919,703), Langley (5,373,904) and/or Scharp et al. (5,322,790) in view of Kearney (5,424,209) and Shuler et al. (5,612,188) These patents do not teach "all of the culture/digestion steps claimed by applicant" as asserted by the Examiner (p. 2). Neither do these patents teach or suggest the process control steps or combinations claimed by the applicant.

Specifically, Mullen teaches placing pieces of pancreas in a container that is "gently agitated in an incubator or a water bath at about 37° using a shaker" (col. 3, lines 12-16). No

other process variables are automatically controlled, and, with pancreatic tissue as a starting material, there is no reason to believe such control would be needed or effective.

Langely teaches that "one or more scales or other measuring devices may be used to compute the rate or volume of flow" (col. 4, lines 68-69). No process variables are automatically controlled.

Similarly, Scharp et al. teach a process in which a "pancreas is incubated at about 37° C. in a double walled stainless steel vessel" (col. 8, lines 60-63) with hot water "circulated between the double walls of the vessel to incubate the pancreas" (col. 8, lines 18-19). No other process variables are automatically controlled. A buffer is used to control pH (col. 3, lines 38-41).

Kearney teaches computer-controlled heating and cooling of a heat sink in which bioreactors are mounted (col. 6, lines 24-41). Means are provided to supply gases (col. 8, lines 66-68) and liquids (col. 10, lines 49-52). "Dissolved oxygen and/or acidity are sensed by indwelling detectors as well as flow cell pH electrodes. On the basis of these data, software controlled decisions are made to refresh the volume of gas in an oxygenator 6" (col. 15, lines 32-35).

Schuler et al. teach a cell culture system in which "the temperature of culture medium in reservoir 50 is regulated by microprocessor 98" (col. 7, lines 36-37), "biological and toxicological reactions/changes in cell culture chambers 56 and 68 are detected by sensors 60 and 72, respectively, and communicated to microprocessor 98" (col. 7, lines 43-45) and "indicator/controller 284a being utilized for pH control, "indicator/controller 284b being utilized

to control dissolved oxygen and indicator/controller 284c being utilized to monitor the temperature within the system" (col. 10, lines 43-46).

The combination of references does not teach that all of the parameters controlled in accordance with the applicants' method claims "are result effective variables" for islet isolation. Just because some of the applicants' claims rely, in part, on structures and steps that are present in the background art does not render the claimed methods and machines (when considered as a whole) obvious. Neither do the cited references contain a suggestion that all of the parameters controlled in the applicants' claims are "all well recognized."

MPEP 2144.03 requires that "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." That is not the case here because the use of "automated/computerized controllers" referred to by the Examiner does not exist in the prior art. Applicant therefore requests that the Examiner "provide documentary evidence in the next Office action if the rejection is to be maintained" as called for by MPEP 2144.03.

It is well settled that just because references can be combined or modified does not render the proposed combination obvious, unless the prior art also suggests the desirability of the combination (MPEP 2143.01). That suggestion does not appear in any of the references cited by the Examiner. In fact, the references teach use of buffers to control pH in islet isolation and stoic acceptance of initial concentrations of other islet processing solution constituents. A reasonable expectation of success of the modification of the references proposed by the Examiner is also

required (MPEP 2143.02) that is not evident from the cited references.

The Examiner appears to be using impermissible hindsight (recognizing the advisability to combine the references only after the inventor has claimed the combination) as the motivation to combine the references. In fact, the prior art teaches away the claimed invention, discouraging persons of ordinary skill from taking the path the applicants' took in addressing the problem solved by the applicants' invention.

The applicants have enclosed with this amendment (as Exhibits A and B) declarations by each of them that show that the art had not solved the problem of automating the islet isolation process when the subject application was filed. The declarations also provide evidence that the claims are supported by the application as filed. The affiants are shown to be persons of ordinary skill in the art.

New apparatus claims 76-79 and 83 and new claim method claims 73-75 and 80-82 are patentable for the same reasons the amended claims are patentable. Linking claims 80 and 83 link the method and apparatus claims. Examination of both groups of claims is respectfully requested.

Based on the above showings, the applicants respectfully request that a timely Notice of Allowance be issued in this case.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required during the entire pendency of this application to Deposit Account No. 500593.

Respectfully submitted,

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